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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,698	08/21/2006	James Phillips	BJS-620-393	5891
23117 NIXON & VAN	7590 04/07/201 NDERHYE, PC	EXAMINER		
901 NORTH G	LEBE ROAD, 11TH F	SRIVASTAVA, KAILASH C		
ARLINGTON, VA 22203			ART UNIT	PAPER NUMBER
			1653	
			MAIL DATE	DELIVERY MODE
			04/07/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
0.66	10/551,698	PHILLIPS ET AL.			
Office Action Summary	Examiner	Art Unit			
	KAILASH SRIVASTAVA	1653			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING D.  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be time will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE	lely filed the mailing date of this communication. (35 U.S.C. § 133).			
Status					
1) ☐ Responsive to communication(s) filed on 25 Ja     2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This     3) ☐ Since this application is in condition for allowal closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
<ul> <li>4)  Claim(s) 1-30 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-30 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Example 11.	epted or b) objected to by the Edawing(s) be held in abeyance. See tion is required if the drawing(s) is obj	e37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) D Notice of References Cited (PTO-892)	4) 🔲 Interview Summary	(PTO-413)			
Notice of References Cited (PTO-892)     Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO/SB/08)     Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite			

## **DETAILED ACTION**

- 1. The amendment, response and remarks filed 24 January 2011 to the Office Action with Non-Final Rejection mailed 24 September 2010 is acknowledged and entered.
- 2. Also acknowledged and entered is the "Supplemental submission" enclosing the "newly executed Declaration" filed 25 January 2011in response to "Oath objected" in Office Action with Non-Final Rejection mailed 24 September 2010.
- 3. Examiner is not clear regarding Applicants' comments for "Rule 75 Objection to Claims 4-22 and 26-30" (See, Response and remarks filed 24 January 2011, Page 7, Lines 18-21) in response cited supra; because no rejection under Rule 75 was made in the Office Action with Non-Final Rejection mailed 24 September 2010.

## **Informals**

- 4. The Art Unit location of your application at the United States Patent and Trademark Office (i.e., USPTO) is changed. Your application (i.e., 10/551,698) has now been assigned to Art Unit 1653. To expedite the prosecution of the instant application (i.e., 10/551,698) and in correlating any papers for the instant application please ensure that all further correspondence regarding the instant application (i.e., 10/551,698) is directed to Art Unit 1653.
- 5. The instant Non-Provisional application (i.e., 10/551,698) currently under prosecution at the USPTO has been assigned to Kailash C. Srivastava in Art Unit 1653. To aid in correlating any papers for the instant application (i.e., 10/551,698), all further correspondence regarding the instant application (i.e., 10/551,698) should be directed to Examiner Kailash C. Srivastava in Art Unit 1653.

## **Claims Status**

- 6. According to the amendment filed 24 January 2011, following is the status of the Claims:
  - 2 Claims 2-3, 5-6, 15, 22 and 29 have currently been amended; and

2 Claims 1-30 are currently pending and are under examination.

#### Withdrawals

- 7. Considering the amendments, and remarks filed 24 January 2011 and Supplemental submission filed 25 January 2011 in response to the Office Action with Non-Final Rejection mailed 24 September 2010, the following objections and rejections in the Office Action with Non-Final Rejection mailed 24 September 2010 are hereby withdrawn:
  - o objection to Specification;
  - o objection to Claims;
  - o objection to Oath; and
  - indefiniteness rejection to Claim 29 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph.

# Claims Objected

- 8. Considering the amendment filed 24 January 2011, following is a new Claims objection.
- 9. Amended Claim 15 is objected to because said claim is written with a blank space between the recitations:
  - "consisting of silicone," at Claim 15, Line 1 and "phosphate glass," at Claim 15, Line 2.

This seems to be a typographical error. Appropriate correction/clarification is required.

# Claim Rejections – 35 U.S.C. §102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-8, 10-12 and 14 are rejected under 35 U.S.C. §102(b) as anticipated by Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005).

In response to above-stated anticipatory rejection in the Office Action with Non-Final Rejection mailed 24 September 2010, Applicants argue, "Reconsideration and withdrawal of the rejection are requested ion view of the following distinguishing remarks."

Following above statement, Applicants have presented a lengthy discussion beginning with the remarks, "The Claims require that tissue growth guides of the Claim (See, Remarks filed 24 January 2011, Page 7, Line 15) to conclude, "The tissue growth guides of the claims are therefore not anticipated by the conduits of Shakesheff (See, Remarks filed 24 January 2011, Page 11, Line 7).

First of all regarding Applicants' remarks that there is no disclosure or suggestion in Shakesheff et al., of the fixing of the hydrogel in the lumen to the conduit., (See, Remarks filed 24 January 2011, Page 8, Lines 18-26); according to the teachings from Shakesheff et al., said conduits are comprised of a core comprising neurite embedded in a biopolymer matrix because collagen is a biopolymer. Neurirte by definition is an undifferentiated or developing neuron, especially in a growing culture. Thus, Shakesheff et al., teach a neuron = nerve cell embedded in the core comprising collagen gel. Said materials are contained in the glass micropipette and include an external sheath (See, Shakesheff et al., Page 5, Lines 14- 16). Additionally, the collagen matrix is a protein and proteins inherently adhere to the glass as an artisan of pertinent art working in a laboratory would specifically know. Thus, the matrix is attached to the glass and therefore the core of the conduit is attached to the glass.

Additionally, Examiner respectfully submits, Applicants admit on record, "the nerve regeneration conduit of Shakesheff does contain all the features of the claimed tissue growth guides" (See, Remarks filed 24 January 2011, Page 8, Lines 12-13).

Applicants' arguments cited supra have been fully and carefully considered, but are not persuasive for the reasons of record at pages 5-6, items 12-13 of the Office Action with Non-

Final Rejection mailed 24 September 2010 and further for the reasons explained in the preceding paragraph, especially in vie of Applicants' statement on record. Therefore, rejection of Claims 1-8, 10-12 and 14 under 35 U.S.C. §102(b) as anticipated by Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005) is maintained and adhered to.

# Claim Rejections - 35 U.S.C. §103

12. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).
- 14. Claims 1-21 and 23-25 are rejected under 35 U.S.C. §103 (a) as obvious over the combined teachings from Kadiyala et al., (US Patent 6, 174,333 B1, See Applicants' IDS filed 09/20/2005) in view of each of Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005) and Chen et al (2000. Peripheral nerve regeneration using silicone rubber chambers filled with collagen, laminin and fibronectin. Biomaterials, Volume 21, pages1541-1547, Applicants' IDS filed 09/30/2005).

In response to above-stated rejection in the Office Action with Non-Final Rejection mailed 24 September 2010, Applicants argue: combined teachings from Kadiyala et al., in view of each of Shakesheff et al., and Chen et al., do not render the instantly claimed invention obvious because one of skill in art would not have combined the references to obtain the claimed invention (See, Remarks filed 24 January 2011, Page 11, Lines 25-28), "self—tensioning tissue growth guide" (See, Remarks filed 24 January 2011, Page 13, Lines 15-16)

Examiner respectfully submits that Applicants are correct in stating that each of Kadiyala et al., Shakesheff et al., and Chen et al., individually do not teach each and every or all the limitations in Claims 1-21 and 23-25. The rejection however, is an obviousness rejection under 35 U.S.C. §103 (a), wherein teachings of each one of the references are combined; because each one of them teach an implant to repair a tissue for securing under tension the tissue adjacent to the defect to be repaired, said defect being in a nerve, which is the motivation present in said references themselves to combine the teachings from each one of Kadiyala et al., Shakesheff et al., and Chen et al.

E.g., Kadiyala et al., teach a central portion encapsulated in a cell containing matrix as a sheet, wherein the matrix is collagen sutures hold themselves and the cell within the collagen matrix with a spring to allow for the tissue cells embedded in the matrix (i.e., mesenchymal stem cells) to grow along the sutures (See, Kadiyala et al., Abstract, Lines 1-14). The Claims as instantly presented do not require the tension after the cells or the implant has grown, wherein the materials are rolled in to a spiral with sutures extending out of the roll (See, Kadiyala et al., Abstract, Lines 12-14).

Furthermore, as explained in the preceding paragraphs and Applicants admitted on record, Shakesheff does contain all the features of the claimed tissue growth guides" (See, Remarks filed 24 January 2011, Page 8, Lines 12-13). Thus, the silence in the teachings of Kadiyala et al., of said growth guides having a sheath is remedied from the teachings of Shakesheff et al. The silence regarding said sheath being constituted of a biosorbable material in the teachings from Kadiyala et al., is clearly remedied from Chen et al's teachings because Chen et al., teach silicone rubber tubes pre-filled with gel substrates containing collagen, fibronectin and laminin, which are art-known constituents to develop and regenerate nerves and for cell adhesion, differentiation, proliferation and neuronal growth (Chen et al., Page 1542, Column 1, Lines 8-24; Figure 2). The silicone rubber tube is the sheath in Chen et al's teachings. Furthermore, each of Kadiyala et al., and Shakesheff et al., also teach the methods to make the instantly claimed growth guide.

Applicants' instantly claimed invention in Claims 1-21 and 23-25 is thus obvious over combined teachings from Kadiyala et al., Shakesheff et al., and Chen et al., because Applicants' arguments that Kadiyala et al., teach a spring to create tension is an argument not required as a limitation in any of the presented Claims 1-21 and 23-25 in the instantly claimed invention.

Please note, the invention Claimed in Claims 1-21 is of a composition in which mechanical tension is produced merely by attachment of the matrix to the sheath and teachings from the reference teach that the core is attached to the sheath during cellular growth (See, Shakesheff et al., and Chen et al).

Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art at the time the invention was made. Note that although each of the Examiner-cited references by themselves may not teach every component in the same order or manner as claimed in the claims under prosecution in the instant application, these references are not relied upon exclusively but in combination. Additionally, the 35 U.S.C. §103 statute does not require that the prior art identically disclose or describe Applicants' invention but rather that no patent should be obtained if the subject matter as a whole would have been prima faciae obvious to persons having ordinary skill in this art at the time the invention was made. In this case, given the teachings from each one of Kadiyala et al., Shakesheff et al., and Chen et al.,; the claimed invention would have been prima faciae obvious to a person of ordinary skill in the art at the time the claimed invention was made.

Applicants' arguments cited supra have been fully and carefully considered, but are not persuasive for the reasons of record at pages 7-10, items 14-16 of the Office Action with Non-Final Rejection mailed 24 September 2010 and further for the reasons explained in the preceding paragraph. Therefore, rejection of Claims 1-21 and 23-25 under 35 U.S.C. §103 (a) as obvious over the combined teachings from Kadiyala et al., (US Patent 6, 174,333 B1, See Applicants' IDS filed 09/20/2005) in view of each of Shakesheff et al., (WO 02/47557 A1, See Applicants'

IDS filed 09/20/2005) and Chen et al (2000. Peripheral nerve regeneration using silicone rubber chambers filled with collagen, laminin and fibronectin. Biomaterials, Volume 21, pages1541-1547, Applicants' IDS filed 09/30/2005 is maintained and adhered to.

15. Claim 22 is rejected under 35 U.S.C. §103 (a) as obvious over the combined teachings from Kadiyala et al., (US Patent 6, 174,333 B1, See Applicants' IDS filed 09/20/2005) in view of each of Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005) and Chen et al (2000. Peripheral nerve regeneration using silicone rubber chambers filled with collagen, laminin and fibronectin. Biomaterials, Volume 21, pages1541-1547) as applied to Claims 1-21 and further in view of Nyberg et al., (1993. Evaluation of a Hepatocyte-Entrapment Hollow Fiber Bioreactor: A Potential Bioartificial Liver. Biotechnology and Bioengineering, Volume 41, Pages 194-203).

In response to above-stated rejection in the Office Action with Non-Final Rejection mailed 24 September 2010, Applicants referring to the discussion regarding rejection of Claims 1-21 and 23-25 over combination of Kadiyala et al., in view of each of Shakesheff et al., and Chen et al., (See, Remarks filed 24 January 2011, Page 11, Line 25 to Page 13, Line16) argue that one of skill in art would not have combined the references to obtain the claimed invention and Nyberg et al., do not over come the deficiencies of said combination of Kadiyala et al., in view of each of Shakesheff et al., and Chen et al (See, Remarks filed 24 January 2011, Page 13, Lines 19-23).

The Examiner respectfully submits, as explained supra, combination of Kadiyala et al., in view of each of Shakesheff et al., and Chen et al., renders the instantly claimed growth guide claimed in Claims 1-21 and 23-25 obvious; but Kadiyala et al., are silent regarding the applicability of said growth guide as a bioreactor for the growth of tissue. Nyberg et al., is added specifically to address the limitation in dependent Claim 22 of applicability of said growth guide as a bioreactor for the growth of tissue.

Nyberg et al., teach a growth guide comprising an inner core constituted of cells in a hydrogel matrix, wherein said hydrogel matrix is collagen. Said cell containing matrix is suspended in a polysulfone hollow fiber, wherein the hollow fiber has an inlet and outlet (Figure

1) so that the matrix may be per fused with a culture medium and said guide is applicable as a bioreactor for growing a tissue (See the title).

Thus, Nyberg et al., in combination with the teachings from Kadiyala et al., in view of each of Shakesheff et al., and Chen et al., teach a growth guide, wherein said growth guide is applicable as a bioreactor for tissue growth.

Applicants' arguments cited supra have been fully and carefully considered, but are not persuasive for the reasons of record at pages 11-12, item 17 of the Office Action with Non-Final Rejection mailed 24 September 2010 and further for the reasons explained in the preceding paragraph. Therefore, rejection of Claim 22 under 35 U.S.C. §103 (a) as obvious over the combined teachings from Kadiyala et al., (US Patent 6, 174,333 B1, See Applicants' IDS filed 09/20/2005) in view of each of Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005) and Chen et al (2000. Peripheral nerve regeneration using silicone rubber chambers filled with collagen, laminin and fibronectin. Biomaterials, Volume 21, pages1541-1547) as applied to Claims 1-21 and 23-25 and further in view of Nyberg et al., (1993. Evaluation of a Hepatocyte-Entrapment Hollow Fiber Bioreactor: A Potential Bioartificial Liver. Biotechnology and Bioengineering, Volume 41, Pages 194-203) is maintained and adhered to.

16. Claims 26-30 are rejected under 35 U.S.C. §103 (a) as obvious over the combined teachings from Kadiyala et al., (US Patent 6, 174,333 B1, See Applicants' IDS filed 09/20/2005) in view of each of Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005) and Chen et al (2000. Peripheral nerve regeneration using silicone rubber chambers filled with collagen, laminin and fibronectin. Biomaterials, Volume 21, pages1541-1547) as applied to Claims 1-21 and additionally in view of additional teachings from Kadiyala et al., (US Patent 6, 174,333 B1, See Applicants' IDS filed 09/20/2005) in view of Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005).

In response to above-stated rejection in the Office Action with Non-Final Rejection mailed 24 September 2010, Applicants referring to the discussion regarding rejection of Claims 1-21 and 23-25 over combination of Kadiyala et al., in view of each of Shakesheff et al., and Chen et al., (See, Remarks filed 24 January 2011, Page 11, Line 25 to Page 13, Line16) request a

clarification regarding the basis to apply each of Kadiyala et al., and Shakesheff et al., as both primary and additional references (See, Remarks filed 24 January 2011, Page 13, Lines 24-26 and Page 14, Lines 6-8) and further request the withdrawal of said rejection in consideration of Applicants' arguments presented for the rejection of Claims 1-21 and 23-25 over combined teachings from Kadiyala et al., in view of each of Shakesheff et al. and Chen et al (See, Remarks filed 24 January 2011, Page 14, Lines 8-10).

The Examiner respectfully submits, Kadiyala et al., is applicable as a **primary reference** for Claims 1-21 drawn to a composition and 23-25 drawn to a method to make said composition. Accordingly, as discussed supra, combination of Kadiyala et al., in view of each of Shakesheff et al., and Chen et al., renders the instantly claimed growth guide and method to prepare said growth guide claimed in Claims 1-21 and 23-25 obvious.

The invention claimed in Claims 26-30 depending from Claim 23, however, is drawn to a method employing additional steps relating to implant the growth guide (i.e., the composition) claimed in Claims 1-21 prepared according to the methods in Claims 23-25 in to a "human or animal body".

For the additional limitation in Claims 26-30 of method to implant said "growth guide", each of Kadiyala et al., and Shakesheff et al., disclose additional teachings exclusively applicable to the method of implanting a growth guide in to a human or animal, which teachings are not applicable to said composition claimed in Claims 1-21 and said method of making said composition in Claims 23-25.

However, said method of implantation encompassed in Claims 26-30 depends from the method of making Claim 23. Accordingly, for the teachings pertinent to the method steps of implanting the "growth guide" in to human or animal, each of Kadiyala et al., and Shakesheff et al., have been applied as "additional references". Examiner has clarified this reasoning in the rejection itself with the statement, "and additionally in view of additional teachings from Kadiyala et al., in view of Shakesheff et al." (Please see, Office Action with Non-Final Rejection mailed 24 September 2010, Page 12, item 18, Line 26).

Applicants' arguments cited supra have been fully and carefully considered, but are not persuasive for the reasons of record at pages 12-13, item 18 of the Office Action with Non-Final Rejection mailed 24 September 2010 and further for the reasons explained in the preceding paragraphs. Therefore, rejection of Claims 26-30 under 35 U.S.C. §103 (a) as obvious over the combined teachings from Kadiyala et al., (US Patent 6, 174,333 B1, See Applicants' IDS filed 09/20/2005) in view of each of Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005) and Chen et al (2000. Peripheral nerve regeneration using silicone rubber chambers filled with collagen, laminin and fibronectin. Biomaterials, Volume 21, pages1541-1547) as applied to Claims 1-21 and additionally in view of additional teachings from Kadiyala et al., (US Patent 6, 174,333 B1, See Applicants' IDS filed 09/20/2005) in view of Shakesheff et al., (WO 02/47557 A1, See Applicants' IDS filed 09/20/2005) is maintained and adhered to.

### Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. §1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

- 18. For the aforementioned reasons, no claims are allowed.
- 19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue X. Liu can be reached at (571)-272-5539 Monday through Friday 9:00 A.M. to 4:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Kaílash C Srívastaval Examiner, Art Unit 1653 (571) 272-0923

/Ralph Gitomer/ Primary Examiner, Art Unit 1657